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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,422	08/10/2001	Gary Van Nest	377882001420	6952

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EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,422	NEST ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-23,48 and 51-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-23,48 and 51-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Final Rejection mailed November 2, 2005 has been vacated.

Response to Amendment

2. Applicants' amendment final filed November 2, 2004 is acknowledged and has been entered. Claims 2, 3, 49 and 50 have been canceled. Claims 24-47 have been withdrawn. Claims 1, 4-23, 48 and 51-84 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This application contains claims 24-47 drawn to an invention nonelected with traverse in the reply filed on September 22, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

5. Claims 1, 4-23, 48 and 51-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-22, 27-29 and 51-62 of copending Application No. 10/214799. Although the conflicting claims are not identical, they are not patentably distinct

from each other because both applications claimed a complex comprising an IMP/MC, immunomodulatory polynucleotide (or oligonucleotide) and a microcarrier, covalently or non-covalently linked, as well as claims to a kit comprising said complex. The complex can also comprise an antigen. The microcarrier can be a liquid phase or solid phase microcarrier. The IMP can vary in length and can comprise a phosphate backbone modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained for the reasons of record. Applicants' *amendment filed November 2, 2004* asserted that "[S]ince this is a provisional obviousness-type double patenting rejection and there are no issued claims, there is nothing to disclaim at this time." This provisional rejection is maintained for the reasons of record.

This rejection is maintained for the reasons of record. Applicants' amendment filed August 17, 2005 has asserted that "[T]his is a provisional obviousness-type double patenting rejection and there are no issued claims. Applicants will address this provisional rejection when there is otherwise allowable subject matter." (see p.11 of Remarks) This provisional rejection is maintained for the reasons of record.

6. Claims 1, 4-23, 48 and 51-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al (WO 98/55495).

The claims are directed to an IMP/MC complex that comprises a polynucleotide (sequence 5'-C, G-3', greater than 6 nucleotides) linked (non-covalently or covalently) to the surface of a microcarrier. The MC is a liquid phase or solid phase or cationic and is less than 10 microns in size. The

polynucleotide may be SEQ ID NO: 1 or have a phosphate backbone modification (phosphorothioate).

Schwartz et al, for example, discloses a complex that comprises an oligonucleotide in conjunction with an immunostimulatory peptide or antigen (abstract; p. 4). The prior art discloses that the complex can also comprise an encapsulating agent that can maintain the ISS and antigen (pp. 7-8; p. 13). Schwartz et al discloses that the oligonucleotides (i.e. ISS or IMP) comprise phosphorothioate backbones, which are phosphate backbone modifications (p. 11; p. 29). Schwartz et al discloses that the oligonucleotide can be combined with immunomodulatory facilitators such as adjuvants, such adjuvants include emulsions and polylactide/polyglycolide microparticles (i.e. MC) (p. 12, 14; claims). Schwartz et al discloses that the ISS can be covalently or non-covalently linked to the immunomodulatory facilitator (i.e. MC) (p. 14). The prior art discloses the nucleotide sequence as set forth in Applicants' SEQ ID NO: 1 (see SEQ ID NO: 15, this sequence contains 22 nucleotides). It is noted that claims 48-84 are directed to a kit. The components of the kit are the same as the components of claims 1-23 and it would appear that Schwartz et al would disclose the claimed kit. Determining the size of the microparticle would have been within the knowledge of a skilled since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Since the Patent Office does not have the facilities for examining and comparing applicants' complex and kit with the complex and kit of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed complex and kit and the

complex and kit of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection of claims 1, 4-23, 48 and 51-84 under 35 U.S.C. § 102(b) as anticipated by Schwartz et al (WO 98/55495) is maintained. This rejection is maintained for the same reasons as the rejection of claims 1-23 and 48-84 under this statutory provision, as set forth in the last Office action. ***Applicant's arguments filed November 2, 2004 have been fully considered but they are not persuasive.*** Applicants have asserted that Schwartz et al describes compositions variously comprising ISS-containing polynucleotides, antigens, and adjuvants, however Applicants respectfully submit that this reference does not anticipate the claimed invention of a complex (IMP/MC) comprising a 5'-CG-3'-containing polynucleotide (IMP) covalently linked to the surface of a biodegradable microcarrier (MC), the polynucleotide is greater than 6 nucleotides in length and the MC is less than 10 μm. However, all of these limitations are found in the prior art of Schwartz et al. Schwartz et al discloses a complex (IMP/MC) comprising a 5'-CG-3'-containing polynucleotide (IMP) (see p. 4, p. 10) covalently linked to the surface of a biodegradable microcarrier (MC) (see p. 12, l. 10-17; p. 12, l. 36-38; p. 14, l. 15-30), the polynucleotide is greater than 6 nucleotides in length (p. 4; p. 10) and the MC is less than 10 μm (see pp.15-16). Schwartz et al also discloses that the complex can comprise an antigen (see claims for example).

Applicants have asserted that although Schwartz et al describes conjugates of immunostimulatory polynucleotides, antigens and/or adjuvants, Schwartz et al does not explicitly describe a complex in which an IMP is covalently linked to the surface of a microcarrier less than 10 μm in size as claimed. However, Schwartz et al at pages 15-16 discloses the size of the microcarrier or microparticle, see p. 16, l. 1-3 specifically. The size range is from 0.04 μm to 100 μm and preferably 0.15 μm to 10 μm Schwartz et al discloses the term immunomodulatory facilitator, which set forth examples such as adjuvants which include alum, lipid emulsions and polylactide/polyglycolide microparticles (p. 14). These are the same polymers/components used in Applicants' microcarrier. Applicants use oil-in-water emulsions, polylactic acid beads, or poly(lactic acid, glycolic acid) copolymers (see specification pp. 11-13). Since the prior art uses the same microcarrier (microparticle) as Applicants it would appear that the microparticle is biodegradable. The prior art discloses the claimed invention.

The rejection of claims 1, 4-23, 48 and 51-84 under 35 U.S.C. § 102(b) as anticipated by Schwartz et al (WO 98/55495) is maintained. This rejection is maintained for the same reasons as set forth in the last Office action. Applicant's arguments filed August 17, 2005 have been fully considered but they are not persuasive. It is noted that Applicants' arguments have been addressed previously. Applicants have invited the Examiner to consider page 15, lines 36-38 of Schwartz et al, "which state that the invention provides compositions and

methods that comprise an encapsulating agent. Continuing on page 16, lines 1-3 state that the microparticles and/or liposomes encapsulating an ISS-IMM are in the form of particles with the recited sizes. The presently claimed invention recites, in part, that the polynucleotide is covalently linked to the surface of a biodegradable MC that is less than 10 μm in size." (p. 12 of Remarks). Schwartz et al discloses that the ISS (i.e. polynucleotides) can be administered in conjunction with immunomodulatory molecules (i.e. antigens) *and/or* immunomodulatory facilitators, which include adjuvants (i.e. microparticles) (p. 12). Schwartz et al discloses that the ISS and the immunomodulatory facilitator (i.e. microparticles) can be administered together in the form of a conjugate (p. 12). The prior art also discloses that immunomodulatory facilitator (i.e. microparticles) can be administered as an ISS-facilitator conjugate, via covalent or non-covalent interactions (p. 14). The prior art anticipates the claimed invention as set forth in claims 1, 4-19, 21, 22, 48, 51-65, 68-76 and 79-82.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the

advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
March 1, 2006